

AUG 30 2004

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**510(k) Premarket Notification Summary
For Owandy SA
EVApal Digital (also known as model K1VSM2000)
Dental Panoramic Sensor**

1. SPONSOR

AFP Imaging Corporation
250 Clearbrook Road
Elmsford, NY 10523

Contact Person: James Johnson
Telephone: (914) 592-6100

Date Prepared: April 27, 2004

2. Device Name

Proprietary Name: EVApal Digital / K1VSM2000 panoramic sensor
Common/Usual Name: Accessory to Extra oral X-Ray System
Classification Name: Extra oral Source X-Ray System Accessory

3. PREDICATE DEVICES

Signet Radiology DXIS

Trophy DigiPan

4. Intended Use

The EVApal Digital / K1VSM2000 System is intended to be used with standard dental panoramic systems such as the Villa Strato X (K002432) X-ray system and Dental Image Management Software computer stations for system operation, archive data storage, image capture and enhancement, and patient data and support by qualified dental professionals.

K041120

5. Device Description

The EVApAn Digital K1VSM2000 System is a digital imaging system in which traditional dental X-ray film has been replaced by a solid-state sensor. The sensor, when exposed to radiation, captures the image in the form of a charge pattern on its surface. The resulting electronic signals are digitized and sent to a computer screen for image presentation.

6. Substantial Equivalence and Technological Characteristics

The EVApAn Digital / K1VSM2000 System is substantially equivalent to the several other Digital Panoramic systems currently legally marketed in United States. The equivalent systems examined are the Trophy DigiPan (K961826, K991912, K012514) and the Signet Radiology DXIS (K983283). The K1VSM2000 System and the predicate devices listed, the Trophy DigiPan and the Signet DXIS, have the same intended use. All are intended to be used with a Dental Panoramic X-ray Source, Dental Image Management Application Software and standard computer hardware for the capture, evaluation, and storage of high quality digital dental X-rays using existing X-Ray equipment. The system and its predicates all consist of an X-ray sensitive solid state imaging array installed in the Dental Panoramic X-ray system in place of the traditional photographic film, connected via cable to digitizing and control electronics which in turn interface to a computer via a standard interface. The proposed and predicate devices are intended for patients receiving routine dental radiography, in a clinical environment by dental professionals.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 30 2004

Mr. James Johnson
Director of Sustaining Engineering
AFP Imaging Corporation
250 Clearbrook Road
ELMSFORD NY 10523

Re: K041120

Trade/Device Name: EVApn Digital / K1VSM2000

Regulation Number: 21 CFR 872.1800

Regulation Name: Extraoral source
x-ray system

Regulatory Class: II

Product Code: 90 MUH

Dated: July 7, 2004

Received: July 9, 2004

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

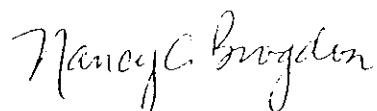
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**510(k) Premarket Notification for
EVApn Digital / K1VSM2000 Dental Panoramic Sensor System**

Page of

510(k) Number (if known): K041120

Device Name: EVApn Digital / K1VSM2000

Indications for Use:

The EVApn Digital / K1VSM2000 Dental Panoramic Sensor is intended to be used with the STRATO Panoramic X-ray System (K002432), manufactured by VILLA SISTEMI MEDICALI S.P.A (registration number 8021091) and a computer work station station for Dental Panoramic Radiographic Imaging.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lippman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041120

Prescription Use ✓
(Per 21 CFR 801.109)